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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/563,055

06/01/2006

Frederic Basset

0512-1315

8679

466 7590 03/24/2009

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EXAMINER

LAM, ANN Y

ART UNIT

PAPER NUMBER

1641

MAIL DATE

DELIVERY MODE

03/24/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/563,055	Applicant(s) BASSET ET AL.	
	Examiner ANN Y. LAM	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 January 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-41 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-14, drawn to a method for the production of a sensor for evaluation of concentration of analyte elements.

Group II, claim(s) 15-41, drawn to a sensor for evaluation of the concentration of analyte elements.

The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature linking groups I and II appears to be that they both relate to a sensor as recited in claim 15, that is a sensor having: a reaction chamber which provides a test volume, the interior of the reaction chamber of which a fraction of a sample is channeled, the reaction chamber having an enclosing reaction surface with a permeable upstream front face and a permeable downstream front face opposite the permeable upstream front face, and a cylindrical impermeable lateral face connected by its two ends to the peripheries of the two upstream and downstream faces; the sensor also having an active component (receptor) which is placed in contact with the fluid sample within the test volume, the receptor elements having an affinity with the analyte elements in order to detect them, and having the property alone or in combination with another active component, indicator, of modifying a measurable extensive state variable (physical and/or chemical) at the time of an event recognition of an analyte element by a receptor element; the sensor also having a transducer system for measurement of the extensive state variable in order to quantify the presence of the analyte elements; wherein the reaction chamber is a multi-microtubular array comprising channels that are parallel and multi-tangent and delimit a plurality of adjacent separate convex volumes; wherein the transducer system is outside the enclosing surface of the reaction chamber and faces the impermeable lateral face, and delivers a measurement that is a summation of the variations of the extensive state variable simultaneously for all the

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elementary volumes through the impermeable lateral face, in such a way as to quantify globally the presence of the analyte elements in the fluid sample in all the channels simultaneously. (It is noted that it is unclear as to what "the joining" means, because it lacks antecedent basis and also because the volumes are separate and thus it is unclear how the volumes are joined. Thus "the joining" is interpreted to mean --in the aggregate--. It is also noted that the "transducer system" can comprise of more than 1 transducer.)

However, Reddy et al., 4,131,798 disclose such a sensor by teaching an apparatus for detecting and counting radioactive particles emanating from discrete samples in a plurality of samples to be analyzed. The apparatus includes a cadmium telluride crystal for each sample providing an electrical pulse signal in direct response to the radioactive particles emanating from the associated sample. Other radioactive particle to electrical pulse signal direct conversion transducers such as silicon or germanium crystals may be utilized as the detector. The pulse output of each direct conversion detector is coupled to a respective storage counter for accumulating the sample counts for each sample so that direct detection and counting is provided simultaneously for each sample in a parallel counting mode. Periodically a computer control unit, in accordance with preset time intervals, sequentially reads the respective accumulated sample count out of each storage counter and couples this information to a control counter for display, if desired, and also to a computer-memory unit for storage and further processing, such as totalling the respective sample count. See column 1, line 64 to column 2, line 19.

As shown in figures 1 and 3, Reddy et al. illustrate apparatus 10 including a detector module 12, counter module 13, and a control module 14 interconnected by a suitable cable such as cable 16 for coupling information therebetween. The detector module 12 includes a plurality of radioactive particle emitting sample positions in an array such as a 4.times.5 matrix, wherein each sample position includes a cup 18 or cavity located in top surface 20 with a radioactive particle detector 22 placed at the bottom of the cup or cavity in contact with the sample or at least immediately adjacent thereto. The detector material may be indium chloride doped cadmium telluride, silicon or germanium crystals for detecting gamma radiation from radio isotopes generated in each sample during, for example, a radio-pharmaceutical assay and providing an electrical pulse output signal for each sample count. See column 2, lines 42-58.

Therefore, the technical feature linking the inventions of groups I and II does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art.

The special technical feature of Group I is considered to be a method including the steps of: channeling a fraction of a fluid sample in the interior of a test volume, the fluid sample being placed in contact with an active component (receptor), which has an affinity with the analyte elements; measuring the variations in the extensive state variable by a transducer system to quantify analyte elements in the form of an

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exploitable analytical signal; the fraction of the fluid sample being multi-channelled in parallel through a reaction chamber comprising a monolithic multi-microtubular array; wherein the transducer system is positioned laterally to the reaction chamber, and carries out an integral measurement that is a summation of the variations in the extensive state variable.

The special technical feature of Group II is considered to be a sensor having: a reaction chamber which provides a test volume, the interior of the reaction chamber of which a fraction of a sample is channeled, the reaction chamber having an enclosing reaction surface with a permeable upstream front face and a permeable downstream front face opposite the permeable upstream front face, and a cylindrical impermeable lateral face connected by its two ends to the peripheries of the two upstream and downstream faces; the sensor also having an active component (receptor) which is placed in contact with the fluid sample within the test volume, the receptor elements having an affinity with the analyte elements in order to detect them, and having the property alone or in combination with another active component, indicator, of modifying a measurable extensive state variable (physical and/or chemical) at the time of an event recognition of an analyte element by a receptor element; the sensor also having a transducer system for measurement of the extensive state variable in order to quantify the presence of the analyte elements; wherein the reaction chamber is a multi-microtubular array comprising channels that are parallel and multi-tangent and delimit a plurality of adjacent separate convex volumes; wherein the transducer system is outside the enclosing surface of the reaction chamber and faces the impermeable lateral face, and delivers a measurement that is a summation of the variations of the extensive state variable simultaneously for all the elementary volumes through the impermeable lateral face, in such a way as to quantify globally the presence of the analyte elements in the fluid sample in all the channels simultaneously.

Accordingly, Groups I and II are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept.

The examiner has required restriction between product and process claims.

Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

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In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Examiner notes that the claims are generally narrative and indefinite, failing to conform with current U.S. practice. They appear to be a literal translation into English from a foreign document and are replete with grammatical and idiomatic errors. For example, claim 1 recites in the preamble a method of production of a sensor, but includes what appears to be a separate sentence reciting a method of evaluation of concentration. Claim 1 in its entirety also appears to be reciting a method of use rather than a method of production. It is also not clear whether or not the language following the term "that is to say" recites positive limitations. Also, as noted above, it is unclear as

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to what “the joining” means, because it lacks antecedent basis and also because the volumes are separate and thus it is unclear how the volumes are joined. Such are examples of the ambiguities of the claims as recited in present form.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANN Y. LAM whose telephone number is (571)272-0822. The examiner can normally be reached on Mon.-Fri. 10-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Mark Shibuya can be reached on 571-272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ann Y. Lam/
Primary Examiner, Art Unit 1641